

REMARKS

Status

Claims 1, 3-15, 18, 19, and 27-31 are pending in the present application. Claims 1, 14, 18, 27, 29, and 31 have been amended. Support for the amendments can be found in at least paragraphs [0084] and [0085] of the specification of the present application as published in U.S. Patent Application No. 2005/0052630. No new matter has been added.

Rejections Under 35 USC 103(a)

Claims 1, 3-15, 18, 19, and 27-31 stand rejected under 35 USC 103(a) over U.S. Patent No. 6,451,002 (“Dev”) in view of U.S. Patent Application No. 2002/0010415 (“Simon”), and in further view of U.S. Patent No. 4,141,359 (“Jacobsen”). Applicant respectfully traverses.

MPEP § 2143 provides that to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest **all the claim limitations**. In this case, the cited references, alone or in combination, fail to teach or suggest all the claim limitations.

Applicant respectfully submits that Dev, Simon, and Jacobsen alone or in combination, fail to teach or suggest a support structure that includes a sterile injection channel adapted to receive a syringe needle, and that the needle electrodes are mounted in an array around the sterile injection channel of the support structure as taught by claim 1 as amended.

Jacobsen teaches topical administration only, based on an iontophoresis device for topical administration of drugs without mechanical penetration. An ionic form of a drug is conducted through epidermal tissue using a DC current. A feedback system is used to maintain a constant current through the epidermal tissue and to avoid excessive voltage (Jacobsen, Abstract). Therefore could not possibly teach needle electrodes or an injection channel.

Simon teaches a system for assessing the performance of a pharmaceutical delivery system, which includes measuring the electrical response of the portion of the body along with the biological response to the pharmaceutical agent (Simon, Abstract). In particular, Simon teaches an electrode and needle holder (Simon, paragraph [0082]); however, there is no mention of a sterile injection channel in Simon, or that the needle electrodes are mounted in an array around a sterile injection channel as claimed.

Dev teaches a method for electrotherapy including an electrode assembly that has a plurality of needles that can be inserted into tissue of a patient. An electrical signal is applied to the electrodes that is proportional to the distance between the electrodes (Dev, column 2, lines 28-55). Applicant respectfully submits that Dev teaches that a pharmaceutical agent is injected into a patient through hollow channels inside each of the electrodes (Dev, column 4, lines 55-64). Thus, in contrast to the claimed invention, in Dev the agent is injected through the electrodes themselves and not through a sterile injection channel between the array of electrodes as taught by claim 1. Even if the hollow channel could be considered a sterile injection channel, it is within each of the electrodes, and therefore the needle electrodes could not be mounted in an array around the sterile injection channel of the support structure as claimed. Moreover, the hollow channels as shown in Figures 3 and 4 of Dev could not possibly be big enough to receive a syringe needle.

Independent claims 27 and 29 teach similar, but not identical, features as claim 1. Applicant therefore respectfully requests that the Examiner withdraw the rejections and allow claims 1, 27, and 29.

With respect to dependent claim 14, Applicant respectfully submits that Simon, Dev, and Jacobsen also fail to teach or suggest that the sterile injection channel extends through a handle. Dev teaches a holder 86 (Dev, column 5, lines 5-11), but the holder is solid and therefore could not possibly teach or suggest that a sterile injection channel extends through it. Simon and Jacobsen have no teachings of handles, and therefore could not possibly teach or suggest such a feature.

Applicant therefore respectfully submits that claim 14 is allowable over the Dev, Simon, and Jacobsen references for the foregoing reasons as well as its dependency on claim 1. Applicant therefore respectfully requests that the Examiner withdraw the rejection and allow claim 14.

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Claims 3-13, 15, 18, 19, 28, 30, and 31 are variously dependent on independent claims 1, 27, and 29, and are therefore allowable for at least the reasons given above for claims 1, 27, and 29. Applicant therefore respectfully requests that the Examiner withdraw the rejections and allow claims 3-13, 15, 18, 19, 28, 30, and 31.

In conclusion, Applicant submits that all pending claims are in condition for allowance and request an early indication of the same. Should the Examiner have any questions that may be addressed through a teleconference, the Examiner is invited to contact the undersigned attorney.

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